UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,880	01/15/2002	Jean-Claude Bystryn	392/25799-DB/RDK	5017

7590 02/23/2006

Robert D. Katz
COOPER & DUNHAM LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,880	BYSTRYN, JEAN-CLAUDE	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *3 and 5-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Re: BYSTRYN, JEAN-CLAUDE

1. The amendment filed 12/01/2005 is acknowledged and entered into the record. Claims 1-9 are pending, claims 3, and 5-9 are withdrawn from further consideration as being drawn to non-elected subject matter.

2. Claims 1,2 and 4 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

4. Applicant is reminded that the priority data needs to be updated in the first line of the specification. Specifically, applicant must indicate the current status of US Application 08/865,112 (see office action mailed 7/27/2005).

Terminal Disclaimer

5. The terminal disclaimer filed on 12/01/2005 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections Withdrawn - 35 U.S.C. § 102

6. The rejection of claims 1,2, and 4 under 35 USC § 102(a) as anticipated by Bystryn *et al* (J. Biol. Resp. Mod. 1986; 5(3):211-224) is withdrawn in view of the persuasive arguments set forth by the applicant and the filing of the declaration by Jean-Claude Bystryn on 12/1/2005.

Claim Rejections Maintained - 35 USC § 103

7. The rejection of claims 1,2 and 4 under 35 USC § 103(a) as being obvious over Albino *et al* (J. Exp. Med. 1981; 154:1764-1778) in view of Gupta *et al* (J. Natl. Cancer Inst. 1984 Jan; 72(1):67-74) is maintained for the reasons of record. Applicant argues that the cited references, whether taken singly or in combination, do not render the instant claims obvious. Specifically, applicant argues that the neither of the cited references are directed to a method of treating melanoma. Applicant contends that Albino discusses antigens taken from multiple cell lines derived from different metastases of the same patient, but fail to discuss the use of the antigens as a vaccine. Applicant states that Albino teaches the examination of the morphology and specifically reports on the phenotypic differences among the cell lines such as growth rate, morphology, pigmentation and expression of surface antigens and glycoproteins. Applicant also contends that Gupta *et al* discusses development of a radioimmunoassay for tumor associated antigens isolated from spent culture media. Applicant indicates that Gupta *et al* fails to mention the use of the antigens to make and use as a vaccine. In addition, applicant contends that the examiner relies on hindsight provided by the instant application to arrive at the instantly claimed invention. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26

USPQ2d 1057 (Fed. Cir. 1993). In the instant case, the claims are drawn to a product *per se* and not a method of treating melanoma as argued. The use of the claimed polyvalent vaccine product for the treatment of melanoma is an intended use. In addition, if the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). In the instant case, because the art appears to teach each of the claimed elements of the invention, the use of the claimed product as a vaccine for the treatment of melanoma is not deemed a patentable distinction or limitation of the claim, but rather as indicated above, an intended use. Specifically, Albino *et al* teaches the characterization of multiple surface antigens on multiple different melanoma cell lines, Gupta *et al* teach that melanoma surface antigens can be recovered in the serum free "spent" media of a cultured melanoma cell line. One of ordinary skill in the art would be motivation to combine the cited references because shed surface antigens derived from multiple different melanoma cells could be purified in the absence culture media containing serum (i.e. FBS) and used as an enriched population of antigenic peptides for eliciting an immune response (as taught by Gupta *et al* see page 72-73, for example).

With regard to the use of hindsight to arrive at the instant invention, "[a]ny judgement on obviousness is in a sense necessarily a reconstruction based on

hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). Applicants may also argue that the combination of two or more references is "hindsight" because "express" motivation to combine the references is lacking. However, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). In the instant case, as indicated above, the claims are drawn to a product *per se* and not to a method. The combination of references cited, teaches the claimed elements of the invention, namely multiple antigens derived from different melanoma cell surface antigen purified from serum free media. Any recitation of an intended use (i.e. for the treatment of a melanoma) is not deemed a patentable limitation.

Therefore, the rejection of claims under 35 USC 103(a) as being obvious is maintained for the reasons of record.

Double Patenting Rejection - Withdrawn

8. The rejection of claims 1,2 and 4 under the judicially created doctrine of obviousness-type double patenting is withdrawn in view of the persuasive arguments and terminal disclaimer filed 12/01/2005.

Conclusion

9. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen, Examiner
Art Unit 1643
February 14, 2006

CHRISTOPHER YAEN
PATENT EXAMINER